IGeneX Inc.

556 Gibraltar Drive
Milpitas, CA 95035
T: (800) 832-3200
F: (408) 935-8272

www.igenex.com

Laboratory Director: Jyotsna S. Shah, Ph.D.

CLIA: 05D0643914
CALIFORNIA: CLF 4033
NPI: 1396837605

REFERRING PHYSICIAN

TEST DOCTOR

TEST PATIENT
DOB:
Gender:
Accession:
Patient ID:

Collected:
Received:
Reported:
Reprinted:
Amended:
Corrected:

BORRELIOSIS - Lyme Disease

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
Lyme ImmunoBlot IgG	Serum			
IGX Criteria:		**Positive**		
CDC/NYS Criteria:		Negative		

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[REVISED REPORT: EFFECTIVE APRIL 10, 2019]

Lyme ImmunoBlot IgG detects antibodies to B. burgdorferi strains and species

Band (kDa)	**18**	**23***	**28**	**30**	**31***	**34***	**39***	**41***	**45**	**58**	**66**	**93***
Intensity	**-**	**+**	**-**	**-**	**-**	**-**	**-**	**+**	**-**	**-**	**-**	**+**

Band Intensity: Positive: + to ++++, Indeterminate: Ind, Negative: (-)

INTERPRETATION	**IGX CRITERIA**	**CDC/NYS CRITERIA**
Positive	2 or more of the starred bands are present (+): 23*, 31*, 34*, 39*, 41*, 93* kDa	5 or more of the following bands are present (+): 18, 23*, 28, 30, 39*, 41*, 45, 58, 66, 93* kDa
Negative	Does not meet IGX criteria for a positive.	Does not meet CDC/NYS criteria for a positive.

LIMITATION: Bands 31* and 34* kDa are present in Lyme vaccinated patients. Viral antibodies cross react with the 93 kDa antigen.

Testing performed at IGeneX 556 Gibraltar Drive Milpitas CA 95035 (800) 832-3200

Diagnosis should not be based on laboratory results alone. Results should be interpreted in conjunction with clinical symptoms and patient history.

NOTE: Western Blots, ImmunoBlots, Lyme Dot Blot, Epitope, PCR, IFA, FISH, C. pneumoniae IgG/IgA, CD57, IGXSpot, Broad Coverage Antibody, COVID-19 Test - These tests were developed and their performance characteristics determined by IGeneX, Inc. They have not been cleared or approved by the FDA. The FDA has determined that such approval is not necessary. These tests are used for clinical purposes and should not be regarded as investigational or for research. IGeneX, Inc. is licensed by CMS and NYS to perform high complexity clinical laboratory testing.

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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
LYME IMMUNOBLOT IGG SPECIATION				
B. burgdorferi US(genus)	Serum	Positive		
B. burgdorferi US spp	Serum	Negative		
BbSs: Borrelia burgdorferi sensu stricto includes but not limited to B. burgdorferi B31 and B. burgdorferi 29				
BbSl: Borrelia burgdorferi sensu lato includes but not limited to B. mayonii and B. californiensis.				
B. burgdorferi European(genus)	Serum	Negative		
B. burgdorferi European Spp	Serum	Negative		
Borrelia burgdorferi European species include but not limited to B. afzelii, B. garinii, B. spielmanii and B. valaisiana.				
B. burgdorferi Species	Serum	Positive		
B. burgdorferi species include but not limited to Bb B31, Bb 297, mayonii, B. californiensis, B. afzelii, B. garinii, B. spielmanii and B. valaisian				

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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
Lyme ImmunoBlot IgM	Serum			
IGX Criteria:		**Positive**		
CDC/NYS Criteria:		**Positive**		

***
[REVISED REPORT: EFFECTIVE APRIL 10, 2019]

Lyme ImmunoBlot IgM detects antibodies to B. burgdorferi strains and species

Band (kDa)	**31***	**34***	**39***	**41***	**93**
Intensity	**+**	**+**	**-**	**+**	**IND**

Band Intensity: Positive: + to ++++, Indeterminate: Ind, Negative: (-)

INTERPRETATION	**IGX CRITERIA**	**CDC/NYS CRITERIA**
Positive	2 or more of the starred bands are present (+): 23*, 31*, 34*, 39*, 41* kDa	2 or more of the following bands are present (+): 23*, 39*, 41* kDa
Negative	Does not meet IGX criteria for a positive.	Does not meet CDC/NYS criteria for a positive.

LIMITATION: Bands 31* and 34* kDa are present in Lyme vaccinated patients. Viral antibodies cross react with the 93 kDa antigen.

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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
LYME IMMUNOBLOT IGM SPECIATION				
B. burgdorferi US(genus)	Serum	Positive		
B. burgdorferi US Spp	Serum	Negative		
BbSs: Borrelia burgdorferi sensu stricto includes but not limited to B. burgdorferi B31 and B. burgdorferi 29				
BbSl: Borrelia burgdorferi sensu lato includes but not limited to B. mayonii and B. californiensis.				
B. burgdorferi European(genus)	Serum	Positive		
B. burgdorferi European Spp	Serum	Negative		
Borrelia burgdorferi European species include but not limited to B. afzelii, B. garinii, B. spielmanii and B. valaisiana.				
B. burgdorferi Species	Serum	Positive		
B. burgdorferi species include but not limited to Bb B31, Bb 297, mayonii, B. californiensis, B. afzelii, B. garinii, B. spielmanii and B. valaisian				
Lyme Serology IgG/IgM	Serum	0.71	Negative: <1.0 Equivocal: 1.0 - <1.2 Positive: >or= 1.2	LIV
Lyme Multiplex PCR - Serum				
Serum - Genomic	Serum	Negative		
Serum - Plasmid	Serum	Negative		
Lyme Multiplex PCR -Whole Blood				
Whole blood - Genomic	W blood	Negative		
Whole blood - Plasmid	W blood	Negative		

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BORRELIOSIS- Relapsing Fever Borrelia

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
TBRF Borrelia ImmunoBlot IgG TBRF Borrelia genus ImmunoBlot IgG Serum		IND	Positive: Detected 2 or more TBRF Borrelia species-specific antibodies. Indeterminate: Detected only 1 TBRF Borrelia species-specific antibody. Negative: No TBRF Borrelia specific antibody detected.	

** TBRF ImmunoBlot IgG detects antibodies to Borrelia hermsii, B. turicatae, B. miyamotoi, B. coriciae and TBRF Borrelia species.*

TBRF Borrelia ImmunoBlot IgG Species

B. miyamotoi	Serum	Negative
B. hermsii	Serum	Negative
B. turicatae	Serum	Negative
TBRF Borrelia spp	Serum	Negative

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
TBRF Borrelia ImmunoBlot IgM TBRF Borrelia genus ImmunoBlot IgM Serum		IND	Positive: Detected 2 or more TBRF Borrelia species-specific antibodies. Indeterminate: Detected species-specific antibody. Negative: No TBRF Borrelia specific antibody detected.	

** TBRF ImmunoBlot IgM detects antibodies to Borrelia hermsii, B. turicatae, B. miyamotoi, B. coriciae and TBRF Borrelia species.*

TBRF Borrelia ImmunoBlot IgM Species

B. miyamotoi	Serum	Negative
B. hermsii	Serum	Negative
B. turicatae	Serum	Negative
TBRF Borrelia spp	Serum	Negative

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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS

RFBorrelia & B.burgdorferi sensu lato RealTime PCR

[REVISED REPORT: EFFECTIVE APRIL 10 , 2019]

Relapsing Fever Borrelia Genus*	Serum	Negative	Negative	

** detects RF Borrelia species specific DNA, including but not limite to B. hermsii, B.turicatae, B. miyamotoi, B. parkeri, B. coriaceae, B. turcica and B. recurrent*

RF Borrelia Subgroup Species**	Serum	Negative	Negative	

*** detects RF Borrelia subgroup species specific DNA including but not limited to B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae and B. recurrentis*

Borrelia burgdorferi sensu lato***	Serum	Negative	Negative	

**** detects B. burgdorferi sl specific DNA including but not limited to B. burgdorferi sensu stricto, B. afzelii, B. garinii, B. californiensis, B. mayonii, B. spielmanii and B. valaisiana*

Borrelia****	Serum	Negative	Negative	

***** detects Borrelia specific DNA including but not limited to B. chiliensis, B. sinica and B. japonica*

DISCLAIMER: Diagnostic value of a negative result is questionable due to low or nonexistent number of Borrelia organisms in patients with Lyme disease

LIMITATION: An inhibition study was performed on about 2000 clinical samples that included fresh whole blood, fresh serum, frozen urine and frozen CSF samples. The inhibition for all sample types was well controlled and only occurred in less than 1% of samples. Therefore, no inhibition control is included in the assay.

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TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS

RFBorrelia & B.burgdorferi sensu lato RealTime PCR

[REVISED REPORT: EFFECTIVE APRIL 10 , 2019]

Relapsing Fever Borrelia Genus*	W blood	Negative	Negative	

** detects RF Borrelia species specific DNA, including but not limite to B. hermsii, B.turicatae, B. miyamotoi, B. parkeri, B. coriaceae, B. turcica and B. recurrent*

RF Borrelia Subgroup Species**	W blood	Negative	Negative	

*** detects RF Borrelia subgroup species specific DNA including but not limited to B. turicatae, B. miyamotoi, B. parkeri, B. coriaceae and B. recurrentis*

Borrelia burgdorferi sensu lato***	W blood	Negative	Negative	

**** detects B. burgdorferi sl specific DNA including but not limited to B. burgdorferi sensu stricto, B. afzelii, B. garinii, B. californiensis, B. mayonii, B. spielmanii and B. valaisiana*

Borrelia****	W blood	Negative	Negative	

***** detects Borrelia specific DNA including but not limited to B. chiliensis, B. sinica and B. japonica*
DISCLAIMER: Diagnostic value of a negative result is questionable due to low or nonexistent number of Borrelia organisms in patients with Lyme disease
LIMITATION: An inhibition study was performed on about 2000 clinical samples that included fresh whole blood, fresh serum, frozen urine and frozen CSF samples. The inhibition for all sample types was well controlled and only occurred in less than 1% of samples. Therefore, no inhibition control is included in the assay.

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BABESIOSIS

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
B. microti IFA - IgM	Serum	<20	< 20 : Negative = 20 : May or may not indicate active infection >=40 : Indicates active infection	Titer
B. microti IFA - IgG	Serum	<40	< 40 : Negative < 160 : May or may not suggest active infection >=160 : Indicates active infection	Titer
Babesia FISH	W blood	Negative		
Babesia PCR				
B. micro	W blood	Negative		
B. dunca	W blood	Negative		

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ANAPLASMOSIS

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
HGA IFA - IgM	Serum	<20	< 20 : Negative = 20 : May or may not indicate active infection >=40 : Indicates active infection	Titer
HGA IFA - IgG	Serum	<40	< 40 : Negative < 160 : May or may not suggest active infection >=160 : Indicates active infection	Titer
HGA(A. phagocytophilum) PCR HGA PCR	W blood	Negative		

EHRLICHIOSIS

HME IFA - IgM	Serum	<20	< 20 : Negative = 20 : May or may not indicate active infection >=40 : Indicates active infection	Titer
HME IFA - IgG	Serum	<40	< 40 : Negative < 160 : May or may not suggest active infection >=160 : Indicates active infection	Titer
HME(Ehrlichia chaffeensis) PCR HME PCR	W blood	Negative		

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RICKETTSIOSIS

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
R. rickettsii IFA - IgG	Serum	<40	< 40 : Negative < 160 : May or may not suggest active infection >=160 : Indicates active infection	Titer
R. typhi IFA - IgG	Serum	<40	< 40 : Negative < 160 : May or may not suggest active infection >=160 : Indicates active infection	Titer
Rickettsia rickettsii and felis/typhi PCR				
Rickettsia rickettsii	W blood	Negative		
Rickettsia felis/typhi	W blood	Negative		

BARTONELLOSIS

TEST	SPECIMEN	RESULT	REFERENCE RANGE	UNITS
B henselae IFA - IgM	Serum	<20	< 20 : Negative = 20 : May or may not indicate active infection >=40 : Indicates active infection	Titer
B henselae IFA - IgG	Serum	40	< 40 : Negative < 160 : May or may not suggest active infection >=160 : Indicates active infection	Titer
B. henselae PCR	W blood	Negative		

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